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"Anchoring Device & its Implementation"

This invention relates to an anchor which can be used in surgical procedures on both humans and animals.

**Background Art**

The invention has application to a wide variety of surgical procedures and one such procedure relates to a method of resolving female incontinence, which involves insertion of a filament which is to be fixed to the ligamentous tissue to either side of the vagina in order to reconstitute the ligamentary support for the urethra and/or vaginal wall. In the past such filaments have either been fixed to the pubic bone or alternatively the rectus abdominus muscle or left "tension free" in that muscle.

The inventor is the principal author of an article entitled "Role of the Pelvic Floor in Bladder Neck Opening and Closure II: Vagina" which appeared in the International Urogynecology Journal (1997) 8:69-73. In that article it was identified the "connective tissue laxity in the vagina or its supporting ligaments is the prime cause of symptoms of stress, urgency and abnormal emptying". As a result in the case of a lax vagina, at least some of the muscular activity which is applied to maintain continence is taken up in resolving the vaginal laxity rather than control of the urethra. Therefore in rectifying the problem it is desirable to establish a situation in which the relationship between the existing muscular and ligamentary support can be re-established

**Disclosure of the Invention**

Accordingly in one aspect the invention resides in a method of providing ligamentary like support between two spaced locations in the body of a patient comprising fixing an anchor in each location, connecting the anchors by a filamentary element, adjusting the tension of the filamentary element between the locations to establish the desired spatial relationship between the locations to provide at least a supplementary ligamentary support between the locations.

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According to a preferred feature of the invention the filamentary element is applied to at least one of the anchors prior to fixation. According to a preferred embodiment of the invention the filamentary element is applied to a pair of anchors at a spacing greater than that desired spatial relationship.

According to another aspect the invention resides in a tissue anchor formed of a material which is compatible for location in human and/or animal tissue, the anchor comprising a base and a head, the head having a configuration to facilitate insertion of the head into tissue and retention of the head in the tissue once inserted, the base formed with an aperture adapted to receive a length of a filamentary element and permit slidable movement of the filamentary element through the aperture in one direction but to restrict movement of the filamentary element through the aperture in the opposite direction.

According to a preferred feature of the invention the aperture is associated with a locking element positioned to extend across the aperture to define a space between the locking element and an opposed edge of the aperture, said space being intended to receive the filamentary element, the locking member having one face proximate the one direction and another face proximate the opposite direction, the locking element intended to cooperate with the filamentary element when in position in the space to restrict the movement of the filamentary element in the opposite direction and to enable movement of the filamentary element in the one direction. According to a preferred feature the edge of the locking element defining the space is formed to engage the surface of the filamentary element when filamentary element is moved in the opposite direction. According to a preferred feature of the invention the edge is defined by a surface extending between the faces of the locking member, the surface being inclined away from the opposed edge of the aperture in the opposite direction. According to a preferred feature of the invention the edge is formed with slots which extend from the face proximate the one direction to at least an intermediate position across the surface. According to a preferred feature of the invention the face of the locking member proximate the one direction is formed as a recess inwardly of the edge. According to a preferred feature the locking member is inclined with respect to the base.

## Claims

The claims defining the invention are as follows:

1. A method of providing ligamentory like support between two spaced locations in the body of a patient comprising fixing an anchor in each location, connecting the anchors by a filamentary element, adjusting the tension of the filamentary element between the locations to establish the desired spatial relationship between the locations to provide at least a supplementary ligamentory support between the locations.
2. A method as claimed at claim 1 wherein the locations comprise ligament and/or muscle tissue.
3. A method as claimed at claim 1 or 2 wherein the anchors are provided with a retaining means adapted to be able to retain the filamentary element in a state of tension between the anchors.
4. A method as claimed at claim 3 wherein the retaining means enables movement of the filamentary element through the anchor to enable the length of the filamentary element between the locations to be shortened but to prevent movement of the filamentary element through the anchors to enable the length of the filamentary element between the applications to be increased.
5. A method as claimed at any one of the preceding claims wherein the filamentary element is not biodegradable over a period of time and is adapted to facilitate the growth of tissue between the locations to provide said ligamentory support between the locations.
6. A method as claimed at any one of the preceding claims wherein the anchor comprises a head having a configuration facilitating insertion into the tissue and retention of the head in the tissue once inserted, the anchor further having a base which is intended to receive the filamentary element, said method comprising inserting the head of the anchor into the tissue with the base buried in the tissue.

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7. A method as claimed at claim 6 wherein the head has a barbed configuration.
8. A method as claimed at claim 7 wherein the barbed configuration comprises a set of prongs extending in a divergent manner from the end of the head towards the base, said prongs being resiliently flexible along their length, said method comprising compressing the ends of the prongs towards each other prior to insertion of the head into the tissue, inserting the head into the tissue and releasing the ends of the prongs once the head is located in the tissue.
9. A method as claimed at claim 6 or 7 or 8 wherein the anchor is associated with a holder which is configured to retain the anchor with the head directed outwardly from the holder, the method comprising installing an anchor in the holder, placing the anchor in position in the tissue by means of the holder and subsequently disengaging the holder from the anchor.
10. A method as claimed at claim 9 wherein the filamentary element is installed in the anchor and the anchor is installed on the holder prior to insertion of the head into the tissue.
11. A method as claimed at claim 9 or 10 as dependant from claim 8 wherein the holder is adapted to receive and support the prongs in their compressed state, said method comprising releasing the prongs from engagement with the holder when the anchor is in position.
12. A method as claimed at claim 9 or 10 or 11 wherein the holder is associated with an insertion appliance, the insertion appliance having a shaft, one end of the shaft adapted to receive the holder, the other end of the shaft supporting the handle, an ejection means extending between the handle and the one end and having a bearing member at one end adapted to bear upon an anchor when installed in the holder, the handle provided with a manipulation member adapted to cause the bearing member to bear on the anchor and cause the displacement of the anchor from the holder, said method comprising locating the holder at the one end of the shaft,

installing an anchor into the holder, placing the anchor in position in the tissue by manipulation of the appliance and on location of the anchor in the tissue, activation of the manipulation means to cause displacement of the anchor from the holder.

13. A method as claimed at any one of the preceding claims wherein the spaced locations comprise the recto-vaginal ligaments or the arcus tendineus ligaments to each side of the vagina and the method resides in the re-establishing of the fascial support for the vagina, said method comprising fixing said anchors into the recto-vaginal ligaments or the arcus tendineus ligaments respectively to each side of the vagina, applying the filamentary element between the anchors and introducing the filamentary element into the fascial tissue such that with time it will become embodied with the fascia and optimally tensioning the filamentary element between the anchors.
14. A method as claimed at any one of the preceding claims wherein the filamentary element is applied to at least one of the anchors prior to fixation.
15. A method as claimed at claim 14 wherein the filamentary element is applied to a pair of anchors prior to fixation at a spacing greater than the desired spatial relationship.
16. A method of providing ligamentory like support between two spaced locations in the body of a patient substantially as herein described
17. A tissue anchor formed of a material which is compatible for location in human and/or animal tissue, the anchor comprising a base and a head, the head having a configuration to facilitate insertion of the head into tissue and retention of the head in the tissue once inserted, the base formed with an aperture adapted to receive a length of a filamentary element and permit slidable movement of the filamentary element through the aperture in one direction but to restrict movement of the filamentary element through the aperture in the opposite direction.

18. A tissue anchor as claimed at claim 17 wherein the aperture is associated with a locking element positioned to extend across the aperture to define a space between the locking element and an opposed edge of the aperture, said space being intended to receive the filamentary element, the locking element having one face proximate the one direction and another face proximate the opposite direction, the locking element intended to cooperate with the filamentary element when the filamentary element is in position in the space to restrict the movement of the filamentary element in the opposite direction and to enable movement of the filamentary element in the one direction.

19. A tissue anchor as claimed at claim 18 wherein the edge of the locking element defining the space is formed to engage the surface of the filamentary element when filamentary element is moved in the opposite direction.

20. A tissue anchor as claimed at claim 19 wherein the edge is defined by a surface extending between the faces of the locking element, the surface being inclined away from the opposed edge of the aperture in the opposite direction.

21. A tissue anchor as claimed at claim 19 or 20 wherein the edge is formed with slots which extend from the face proximate the one direction to at least an intermediate position across the surface.

22. A tissue anchor as claimed at any one of claims 19 to 21 wherein the edge of the locking element has a convex arcuate configuration.

23. A tissue anchor as claimed at any one of claims 18 to 22 wherein the space has a configuration substantially corresponding to the cross section of the filamentary element.

24. A tissue anchor as claimed at claim 23 wherein the space has a configuration corresponding to the cross sectional configuration of the filamentary element when under longitudinal tension.

25. A tissue anchor as claimed at any one of claims 18 to 24 wherein the space has a part annular configuration.
26. A tissue anchor as claimed at any one of claims 18 to 25 wherein the space is located substantially centrally across the central longitudinal axis of the anchor.
27. A tissue anchor as claimed at any one of claims 18 to 26 wherein the face of the locking member proximate the one direction is formed as a recess inwardly of the edge.
28. A tissue anchor as claimed at any one of claims 17 to 27 wherein the locking member is inclined with respect to the base.
29. A tissue anchor as claimed at any one of claims 17 to 28 wherein the head has a barbed configuration.
30. A tissue anchor as claimed at claim 29 wherein the barbed configuration of the head is defined by a set of prongs, said prongs being located in substantially equi-distant spacing around the central axis of the head, said prongs being divergent away from the end of the head in the direction of base.
31. A tissue anchor as claimed at claim 30 wherein the prongs are of a tapered configuration.
32. A tissue anchor as claimed at claim 31 wherein the outer end of the prongs are pointed.
33. A tissue anchor as claimed at any one of claims 30 to 32 wherein the prongs are resiliently flexible along their length.
34. A tissue anchor substantially as herein described with reference to the accompanying
35. A holder adapted to support the anchor as claimed at any one of claims 17 to 34 comprising a socket configured to clampingly receive the base, the

socket being configured to allow access to the aperture, the clamping engagement between the holder and the base being such that on relative movement between the holder and the anchor the anchor is able to be disengaged from the holder.

36. A holder as claimed at claim 35 wherein the base has a substantially laminar-like configuration comprising two opposed substantially parallel faces.
37. A holder as claimed at claim 35 wherein the socket comprises a pair of spaced elements which receive opposed sides of the base with the aperture between the spaced elements.
38. A holder as claimed at claim 36 wherein the socket comprises a pair of spaced elements which receive opposed sides of the base with the aperture between the spaced elements.
39. A holder as claimed at claim 35 or 37 wherein the socket is defined by a set of boss elements which are configured to receive the free ends of the prongs of the tissue anchor as claimed at any one of claims 30 to 34 when compressed radially with respect to the central axis of the anchor.
40. A holder as claimed at any one of claims 35 to 39 supporting the anchor of is provided as a single element.
41. A holder as claimed at claim 40 including a length of said filamentary element supported by the anchor.
42. A pair of holders of the form as claimed at claim 41 supporting between themselves the length of the filamentary element.
43. A holder substantially as herein described with reference to the accompanying drawings.
44. An insertion appliance comprising a shaft adapted to accommodate at one end the holder as claimed at any one of claims 35 to 40, the other end of

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the shaft supporting a handle, an ejection means extending between the one end and the handle, a bearing member provided at the one end and a manipulation means provided adjacent the handle whereby on an anchor of the form as claimed at any one of claims 17 to 34 being installed in the holder and on activation of the manipulation means the bearing member will bear upon the anchor to move the anchor from engagement with the holder.

45. An insertion appliance as claimed at claim 41 supporting the holder as and the holder supporting the anchor is provided as a single element.
46. An insertion appliance as claimed at claim 40 wherein the insertion supports a holder of the form described above having an anchor of the form described above applied thereto are provided as a single element.
47. An insertion appliance as claimed at claim 46 including a length of said filamentary element supported by the anchor.
48. A pair of insertion appliances of the form as claimed at claim 47 supporting between themselves the length of the filamentary element.
49. An insertion appliance as claimed at claim 47 provided with a pair of said holders which support between themselves the length of the filamentary element.
50. An insertion appliance substantially as herein described with reference to the accompanying drawings.